

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action are respectfully requested in view of the following reasons. Claims 1-18 are pending in this application.

Rejections Under 35 U.S.C. §101

Claims 1-18 stand rejected under 35 U.S.C. §101 as being allegedly drawn to non-statutory subject matter.

Claim 1 defines a saddle clamp for mounting on a bone with a curved surface in a bone fixing or spinal fusion operation, for carrying a bone-fixing member, the saddle clamp having a rigid body with at least two holes for passing fixing elements to be tightened to the bone and at least one assembly element integral with the body for attaching the bone-fixing member, the rigid body having a contact surface configured to have at least three points of contact with the curved surface of the bone when the saddle clamp is mounted thereon, at least two of the holes passing through the contact surface at least adjacent to two of the three points of contact so as to provide, upon tightening of the fixing elements, at least three spaced apart, non-collinear areas of contact and thereby firm attachment of the clamp to the bone.

Claims 1-18 stand rejected as being drawn to non-statutory subject matter, citing the recitation in claim 1 of “two of said three points of contact [with said curved surface of bone].” Applicant assumes that this rejection has been made based on misunderstanding in that the broadest reasonable interpretation of the claimed subject matter is directed to a human being as a whole, which does not meet the requirements of 35 U.S.C. §101.

However, Applicant respectfully notes that claim 1 does not encompass a human being. Rather, claim 1 clearly defines that “the rigid body [of the saddle clamp] has a contact surface configured to have at least three points of contact” with part of a bone. The points of contact, rejected by the Office Action as constituting a non-statutory subject matter, in fact constitute *portions of the saddle clamp*, and NOT of a bone.

Accordingly, Applicant respectfully submits that claim 1 is in compliance with 35 U.S.C. §101. Thus, claim 1, and claims 2-18 dependent therefrom, are allowable for at least this reason.

Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. §101 rejection of claims 1-18.

Rejections Under 35 U.S.C. §102

Claims 1-3 and 5-8 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by U.S. Patent No. 6,235,033 issued to Brace *et al.* ("Brace"). Applicant respectfully traverses this rejection for at least the following reasons.

In order for a rejection under 35 U.S.C. §102(b) to be proper, a single reference must disclose every claimed feature. To be patentable, a claim need only recite a single novel feature that is not disclosed in the cited reference. Thus, the failure of a cited reference to disclose one or more claimed features renders the 35 U.S.C. §102(b) rejection improper.

Brace discloses a bone fixation assembly comprising a bone fixation device (10), such as bone plate, having through holes (12). Bushings (14) having slots (28) are provided in the holes. Fastening screws (32) are provided to be threaded into the bone passing through the bushings. The radial wall (44) of each fastening screw is provided with at least one slit (46) to enable outward expansion thereof. A head (38) of each fastening screw is open-ended at the top, and includes a recess (50) with a threaded inner surface. A locking screw (34) is provided which may be inserted, i.e. threaded, into the recess, thus expanding the radial wall of the fastening screw, and locking it into place.

With regard to claim 1, the Office Action concludes that Brace teaches a saddle clamp having a rigid body having a contact surface (Fig. 1, element 10) with at least two holes (Fig. 3, element 24, and the holes indicated in Fig. 2), at least one assembly element (Fig. 12, element 34) with at least two of the holes passing through the contact surface (Fig. 1).

First, Applicant respectfully notes that the Office Action equated a saddle clamp and a bone fixation assembly, while claim 1 refers to a saddle clamp only. A saddle clamp has a

specific geometry, i.e. having, *inter alia*, a surface such as a hyperbolic paraboloid which contains one or more saddle points. This is consistent with the definition of a saddle surface, for example, as explicated on page 10, lines 19-21 of the application as filed:

The saddle surface 56 is defined generally between a down-turned arch 60 and an upturned arch 62 lying in transverse planes and having a common point 64 (saddle point).

Thus, claim 1 specifically defines a clamp (which may constitute part of a bone fixation assembly) which has a saddle surface, for mounting on a bone. Brace does not make any reference to such a surface, either in the specification thereof or in the drawings. The bone fixation device illustrated in Brace has a surface having two down-turned arches having a common point. Because Brace does not disclose a clamp having a saddle surface, which is implicit in the term “saddle clamp,” especially with reference to the specification as cited above, this 35 U.S.C. 102(b) rejection is improper.

Besides the features inherent in the definition of “saddle clamp,” Brace does not disclose or suggest all of the features of claim 1 as noted below.

The Office Action refers to element 34 of Brace as anticipating the assembly element defined in claim 1, without any further explanation. However, Applicant respectfully notes that claim 1 defines that the assembly element is “integral with [the] body” of the saddle clamp. The Office Action further referred to element 10 (the bone fixation device) as anticipating the rigid body of the saddle clamp. Consequently, in order for Brace to anticipate claim 1 as specified by the Office Action, element 34 (the locking screw) should be integral with the bone fixation device. Moreover, the locking screw 34 according to Brace is not even intended to come into contact with the bone fixation device 10. Furthermore, it is against the teachings of Brace for any of the other elements to be integral with the bone fixation device. Rather, the non-integral formation of the elements of the bone fixation assembly according to Brace “allows for a surgeon-selected angle of a fastening screw relative to the fixation device and locking of the

fastening screw once the screw is at the desired orientation” (Col. 1, lines 52-55). Forming any of the elements integral to one another would prevent the assembly from performing the stated function, and would therefore be against the general teachings of Brace.

Moreover, the Office Action makes no reference to the feature of Claim 1 that “at least two of said holes passing through said contact surface at least adjacent to two of said three points of contact so as to provide, upon tightening of said fixing elements, at least three spaced apart, non-collinear areas of contact and thereby firm attachment of said clamp to said bone.” Brace does not disclose an element which is adapted to establish three spaced apart, non-collinear areas of contact by tightening fixing elements in two points of contact, as required by claim 1.

At least in view of the above, it is clear that Brace fails to anticipate claim 1. Thus, claim 1 is allowable. Claims 2, 3, and 5-8 depend from claim 1, and thus, are allowable for at least this reason. However, at least some of claims 2, 3, and 5-8 have their own features patentably distinguishable over Brace as noted below.

Claim 3 stands rejected as being anticipated by Brace, positing that it reads on element 34 (the locking screw) as illustrated in Fig. 6.

The locking screw of Brace is a distinct element from the bone fixation device (as stated above, the Examiner considers the bone fixation device of Brace to anticipate the rigid body of the claims of the present application). This is clear from even a cursory reading of Brace, and is seen in Fig. 6. Thus, it could not accurately be described as “protruding from” it, as required by claim 3. In addition, Brace relates to the undesirability of either the fastening screw 32 or the locking screw 34 from protruding from the bone fixation device (*See, e.g.,* Col. 4, lines 17-25). Thus, providing the locking screw of Brace as protruding from the bone fixation device is against the teachings of Brace.

Claims 5 and 7 stand rejected as being anticipated by Brace, positing that Brace discloses a saddle shaped surface with first and second passing holes.

In connection with the feature of a saddle shaped surface, the Examiner is asked to refer

Applicant's remarks note above with regard to claim 1.

Applicant respectfully submits that, however, the Office Action makes no reference to other features of claims 5 and 7. For example, claim 5 defines that the contact surface of the rigid body is adapted to "straddle the top of the pedicle [of a vertebra] between the transverse process and the superior facet when said saddle clamp is mounted," while simultaneously contacting the superior facet of the vertebra. The bone fixation device of Brace is not disclosed as being so adapted, nor is it evident from the figures of Brace that this is the case.

Because Brace fails to disclose, teach, or suggest every feature as claimed, it does not anticipate claims 1-3 and 5-8. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of claims 1-3 and 5-8.

Rejections Under 35 U.S.C. §103

Claim 4 stands rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Brace in view of U.S. Patent Application Publication No. 2003/0135210 applied for by Dixon ("Dixon"). Applicant respectfully traverses this rejection for at least the following reasons.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the reference or references, when combined, must disclose or suggest all of the claim limitations. The motivation to modify the prior art and the reasonable expectation of success must both be found in the prior art and not based upon a patent applicant's disclosure. See in *re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claim 4 stands rejected as being obvious over Brace in view of Dixon, positing that the threaded nut defined in claim 4 reads on a feature defined in paragraph 42 of Dixon.

Claim 4 depends from claim 1, and Dixon fails to cure the deficiencies of Brace noted above with regard to claim 1. Specifically, Dixon also fails to teach or suggest the saddle clamp and other features of claim 1. Hence, claim 4 is allowable at least because it depends from an

allowable claim 1.

However, claim 4 is allowable over the two references even in view of its own features as noted below.

Dixon refers to two nuts, indicated therein at 48 and 49. Because neither of them is built into a rigid body, it is not clear how this feature teaches the feature a “threaded nut built into said rigid body,” as required by claim 4. Furthermore, claim 4 defines that the threaded nut constitutes the assembly element recited in Claim 1, which is “for attaching said bone-fixing member” to the saddle clamp. The nuts disclosed in Dixon do not fulfill this function.

Moreover, it is not proper to modify Brace by including therein either of the nuts of Dixon. The operation of Brace entails passing the fastening screws 32 through the bushings 14, then threading a locking screw 34 in the head 38 of each fastening screw, thereby deforming it, increasing the interlocking between the bushing and the fastening screw (*See*, e.g., Col. 4, line 67-Col. 5, line 5). The use of a nut, as disclosed in Dixon, precludes this operation, and thus, is against the teachings of Brace.

Accordingly, claim 4 is not obvious over Brace and Dixon, whether taken alone or in combination.

Claim 9 stands rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Brace. Applicant respectfully traverses this rejection for at least the following reasons.

Applicant respectfully submits that claim 9 is allowable over Brace at least because it depends from claim 1, which is allowable over Brace as noted above.

Claims 10 and 12 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Brace in view of Dixon (“Dixon”). Applicant respectfully traverses this rejection for at least the following reasons.

Claims 10 and 12 depend from claim 1, and Dixon fails to cure the deficiencies of Brace noted above with regard to claim 1. Specifically, Dixon also fails to teach or suggest the saddle clamp and other features of claim 1. Hence, claims 10 and 12 are allowable at least because it

depends from an allowable claim 1.

However, claims 10 and 12 are allowable over the two references even in view of their own features as noted below.

Claims 10 and 12 stand rejected as being obvious over Brace in view of Dixon, positing that Dixon discloses the method steps defined in claim 10, while Brace discloses the clamp. With reference to claim 12, the Office Action posits that Brace teaches vertebra which constitute, owing to the presence of the spinal cord running therethrough, tubular bones.

First, Applicant respectfully objects to the combination of Brace and Dixon to reject claims 10 and 12. As noted above, employing the method of Dixon with the device of Brace will not be operative, since Brace discloses a deformation of the elements thereof, and the device of Dixon is not suited for such operation.

Because the combined references do not work, the rejection of claim 10 is traversed at least in view of our arguments presented above in connection with claim 1 with reference to Brace. With respect to claim 12, Applicant respectfully notes that Brace makes no reference to the configuration of the bone, and thus, it does not disclose a tubular bone. Furthermore, it makes no reference to a vertebra.

Moreover, Applicant respectfully disagrees with the Examiner's characterization of a vertebra as a tubular bone due to the presence of the spinal cord. While the spinal cord may indeed be considered tubular, it is not a bone. The arrangement of a plurality of vertebra arranged along a tubular member, i.e. the spinal cord, to form the vertebral column does not render each component vertebra as a tubular bone.

Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection of claims 4, 9, 10, and 12. Since none of the other prior art of record, whether taken alone or in any combination, discloses or suggests all the features of the claimed subject matter, Applicant respectfully submits that independent claim 1, and all the claims that depend therefrom, are allowable.

CONCLUSION

Applicant believes that a full and complete response has been made to the pending Office Action and respectfully submits that all of the stated grounds for rejection have been overcome or rendered moot. Accordingly, Applicant respectfully submits that all pending claims are allowable and that the application is in condition for allowance.

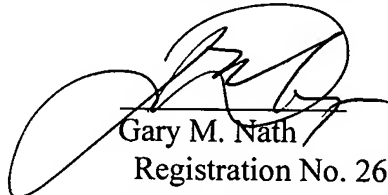
Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicant's undersigned representative at the number below to expedite prosecution.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,
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